

Appl. No. 10/825,961
Amdt. dated October 4, 2006
Reply to Office Action of August 16, 2006

PATENT

Amendments to the Drawings:

Figs. 1D, 6A, and 6B have been amended to correct the numbering errors noted by the Examiner. In particular, reference numeral 4 has been changed to reference numeral 6 in Fig. 1D. Reference numerals 62a and 62b have been changed to 62 in both Fig. 6A and 6B.

Attachment: Replacement Sheet
Annotated Sheet Showing Changes

REMARKS/ARGUMENTS

Claims 1-130 were pending. The claims have been amended and canceled as noted above. Re-examination and reconsideration of the claims, as amended, are respectfully requested.

As an initial matter, Applicants thank Examiner Rodriguez for the helpful and courteous interview on September 6, 2006. At that interview, Applicants discussed teachings of the Sharkey patent and the Hoch patent. Applicants further discussed possible amendments to the method claims which would clarify that the catheter is anchored after it has been positioned so that the patient can move after positioning without dislodging the catheter.

With respect to the Election of Species requirements, Applicants believe that independent claims 1 and 35, as amended, are in condition for allowance and thus believe that dependent claims 2-34 and 35-63 will depend from an allowable independent claim, thus allowing them to remain in the application. Withdrawn claims 64-130 have been canceled without prejudice to refiling in a subsequent divisional application.

The objection to claim 63 has been overcome by correcting the dependency.

The objections to the drawings have been overcome by correcting the reference numerals in Figs. 1D, 6A, and 6B, as noted by the Examiner. Applicants apologize for these errors.

Turning now to the substantive rejections, independent claim 1 as well as claims 2, 6-8, 11-13, 15, 22, 23, and 33 were rejected as being anticipated by the Sharkey '087 patent. Such rejections are traversed in part and overcome in part.

Claim 1, before amendment, set forth a three-method step where a catheter device is positioned in a disc, a distal portion of the catheter is anchored to maintain the portion in the disc, and at least one substance is introduced into the disc through the catheter device.

Applicants believe that Sharkey fails to teach such a three-step protocol. The most pertinent teaching in Sharkey appears to be at lines 51-62 of Column 12, where it is taught that a catheter 500 as shown in Fig. E may be used for a variety of treatment modalities, including "diagnostic delivery of fluoroscopic solutions." While it is true that this passage

teaches that a substance is to be delivered, nowhere does Sharkey '087 ever teach that it's delivered into a disc (as opposed to surrounding the disc to permit fluoroscopic observation). Nor does Sharkey ever teach that a distal portion of the catheter 14 is ever anchored, in a disc or elsewhere in or around the disc space. Thus, Applicants believe that Sharkey '087 falls far short of anticipating claim 1, even prior to amendment.

In an effort to expedite prosecution of the subject application, however, and as discussed at the interview, Applicants have amended claim 1 to clarify that the distal portion of the catheter device is anchored "after it has been positioned" in the disc and further that "the distal portion remains anchored even when the patient changes positions." Finally, claim 1 further sets forth that at least one substance is introduced "while the distal portion remains anchored in the disc."

As recognized by the Examiner in the interview, Sharkey does not teach that the catheter is anchored after it has been positioned nor that the anchoring will remain even while the patient changes positions and a substance is being introduced. For these reasons, it is believed that independent claim 1 as well as all claims dependent thereon distinguish over Sharkey et al., even when combined with Hoch as discussed below.

Independent claim 35, the only other pending independent claim, was rejected as being obvious over the combination of Sharkey et al. in view of Hoch '518. Such rejections are traversed in part and overcome in part. The Examiner argues that Hoch teaches a number of claim elements which are absent from Sharkey, including causing the patient to assume a position in which substantial spinal pain is experienced before introducing the at least one substance. Upon discussion with the Examiner at the interview, the Examiner clarified that she was referring to the teaching in Hoch that the patient "was placed in a prone position" as taught for example in paragraph 39 of Hoch.

The patient's assumption of a prone position, of course, was intended to permit access to the back for inserting the catheter of Hoch as described more fully in the remainder of paragraph 39. There was no intention in Hoch to have the patient assume a position in which pain would be experienced after the catheter was introduced and the substance introduced through the catheter.

Even if Hoch were assumed to teach delivery of a substance to a patient's spinal region in connection with having the patient assume painful positions, Hoch still does not teach delivering substances into a disc nor that the catheter be anchored. Indeed, the teachings of Hoch specifically deal with a steerable catheter which would presumably remain available for repositioning to allow the pain medication to be delivered to different regions within the epidural vertebral space (but not within the disc itself).

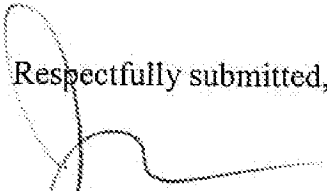
Nonetheless, Applicants have amended independent claim 35 to even further distinguish Hoch and the combination of Hoch with Sharkey. Claim 35 has been amended to clarify that the distal portion of the catheter is anchored after it's positioned in a disc and further that the analgesic or anesthetic is introduced "either before or after the patient has assumed the position, where the patient observes whether the analgesic or anesthetic has reduced the pain experienced."

CONCLUSION

For these reasons, Applicants believe that independent claim 35 clearly distinguishes the combination of Sharkey and Hoch, and request that claim 35 as well as all claims dependent thereon be allowed.

If for any reason the Examiner believes that a telephone conference would in any way expedite prosecution of the subject application, the Examiner is invited to telephone the undersigned at (650) 326-2400.

Respectfully submitted,


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Attachments: *2 sheets Annotated Drawing and/ Replacement Sheets*

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